



State of California—Health and Human Services Agency
Department of Health Care Services



November 15, 2019

Mr. Richard C. Allen, Director
Western Regional Operations Group
Centers for Medicare & Medicaid Services
San Francisco Regional Office
90 Seventh Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

STATE PLAN AMENDMENT 19-0015: CHANGES TO BLOOD FACTORS
REIMBURSEMENT

Dear Mr. Allen:

The Department of Health Care Services (DHCS) is submitting State Plan Amendment (SPA) 19-0015 for your review and approval. This SPA proposes to modify the Medi-Cal Fee-For-Service (FFS) reimbursement methodology for blood factors in the California Medicaid State Plan.

The Centers for Medicare & Medicaid Services (CMS) published its Final Rule on Covered Outpatient Drugs (CODs) on February 1, 2016, (81 Fed.Reg. 5170). This rule implements provisions of the 2010 Patient Protection and Affordable Care Act pertaining to Medicaid reimbursement for CODs, and requires states to document the blood factor reimbursement methodology as part of the State Plan.

The target effective date for SPA 19-0015 is July 1, 2020.

A Public Notice was published on March 19, 2019. A copy of that notice is enclosed.

DHCS determined that there is no impact to Indian Health Programs and Urban Indian Organizations with this SPA, and submitted a No Notice Request to CMS on March 15, 2019. CMS provided approval of the request on March 19, 2019. The No Notice Request and subsequent approval are enclosed in this SPA packet.

Mr. Richard C. Allen
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If you have any questions regarding the SPA, please contact Harry Hendrix, Chief, Pharmacy Benefits Division, at (916) 552-9500 or via e-mail at Harry.Hendrix@dhcs.ca.gov.

Sincerely, 

Mari Cantwell
Chief Deputy Director
Health Care Programs
State Medicaid Director

Enclosures

cc: Ms. Jacey Cooper
Senior Advisor
Health Care Programs
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Ms. René Mollow
Deputy Director
Health Care Benefits & Eligibility
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Ms. Erica Bonnifield
Assistant Deputy Director
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Mr. Harry Hendrix, Chief
Pharmacy Benefits Division
Department of Health Care Services
Harry.Hendrix@dhcs.ca.gov

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

1 9 — 0 0 15

2. STATE

California

3. PROGRAM IDENTIFICATION:

Title XIX of the Social Security Act (Medicaid)

TO: REGIONAL ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

07/01/2020

5. TYPE OF PLAN MATERIAL (*Check One*)☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENTCOMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION

42 CFR Part 447 Subpart I - Payment for Drugs

7. FEDERAL BUDGET IMPACT

a. FFY 2020 \$ (1.25 million)b. FFY 2021 \$ (5 million)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Supplement 2 to Attachment 4.19-B, page 9

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (*If Applicable*)

Supplement 2 to Attachment 4.19-B, page 9

10. SUBJECT OF AMENDMENT

Proposed Changes to Blood Factors Reimbursement

11. GOVERNOR'S REVIEW (*Check One*)☐ GOVERNOR'S OFFICE REPORTED NO COMMENT☒ OTHER, AS SPECIFIED☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL

13. TYPED NAME

Mari Cantwell

14. TITLE

State Medicaid Director

15. DATE SUBMITTED

November 15, 2019

16. RETURN TO

Department of Health Care Services

Attn: Director's Office

P.O. Box 997413, MS 0000

Sacramento, CA 95899-7413

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

18. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

22. TITLE

23. REMARKS

For Box 11 "Other, As Specified," Please note: The Governor's Office does not wish to review the State Plan Amendment.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR CLOTTING FACTOR

1. Clotting factor is defined as coagulation factors and their recombinant analogs.
2. Payment for clotting factor purchased through and dispensed by a federally recognized hemophilia treatment center (HTC) or its contracted pharmacy will be the lower of:
 - a. The HTC's actual acquisition cost for the drug as defined in Welfare and Institutions Code section 14105.46, plus a professional dispensing fee of \$0.14 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a), plus 20%.
3. Payment for clotting factor purchased outside of a federally recognized HTC and dispensed by specialty pharmacies, Centers of Excellence, or any other provider will be the lower of:
 - a. The provider's actual acquisition cost for the drug equal to invoice price minus any discounts (excluding a prompt pay discount of less than, or equal to 2%), rebates, or chargebacks, plus a professional dispensing fee of \$0.04 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a) plus 20%.

This payment methodology is applicable to both pharmacy and non-pharmacy clotting factor claims.